UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LATIESE MILLS, **Plaintiff,** **v.** **ETHICON, INC.; JOHNSON & JOHNSON; C.R. BARD INC.; DAVOL, INC.; ATRIUM MEDICAL CORP.; MAQUET CARDIOVASCULAR, LLC; GETINGE AB; COVIDIEN, INC.; COVIDIEN LLC; COVIDIEN PLC; COVIDIEN AG; SOFRADIM PRODUCTIONS; and JOHN DOE CORPORATIONS 1-100, inclusive,** **Defendants.**	Civ. No. 17-12624-KM-MF **OPINION**

KEVIN MCNULTY, U.S.D.J.:

Before the Court are two motions to dismiss the complaint: one filed by defendants Atrium Medical Corporation ("AMC") and Maquet Cardiovascular, LLC ("Maquet") (DE 25), and the other filed by Getinge AB, a Swedish corporation. (DE 26).

In March of 2013, the plaintiff, Latiese Mills, who is a citizen of Pennsylvania, underwent an abdominal hernia repair surgery, and was implanted with a hernia mesh device. In November of 2015, she went to the hospital to repair a recurrent ventral hernia. During that procedure, it was revealed that Mills "had developed a seroma" and that the mesh implant device had "adhered to her bowels," resulting in significant injuries. Mills's six-count complaint alleges various products liability claims related to the hernia mesh device.

AMC and Maquet seek dismissal of the complaint pursuant to Federal Rule 12(b)(6) on the grounds that the complaint fails to meet pleading standards for statement of a claim. They also contend that Pennsylvania law applies to the complaint, and that Pennsylvania law does not recognize strict liability or warranty claims in medical device products liability cases.

Getinge AB, the Swedish corporate parent of AMC and Maquet, joins in AMC and Maquet's motion. Getinge AB also contends that service was defective and that it is not subject to personal jurisdiction in New Jersey. Specifically, it objects that Mills mailed a copy of the complaint and summons to Maquet, Getinge AB's domestic subsidiary, and did not translate the complaint into Swedish as required by the Hague Convention.

For the reasons provided below, the following claims are dismissed with prejudice as to all defendants because they are invalid as a matter of law: strict liability for defective design (second count); strict liability for failure to warn (third count); breach of the implied warranty of fitness for a particular purpose (fifth count); and breach of the warranty of merchantability (sixth count). The remaining counts, negligence and breach of an express warranty, are dismissed without prejudice for failure to state a claim.

I also conclude that service on Getinge AB by mailing a copy of the summons and complaint to Maquet (Getinge AB's in-state subsidiary) was deficient. Accordingly, dismissal of the complaint as to Getinge AB is warranted for this additional reason. This dismissal is without prejudice.

I. Factual Background[1]

In March of 2013, Mills underwent an abdominal hernia repair surgery at Pennsylvania Hospital in Philadelphia and was implanted with "a hernia mesh device." (Compl ¶36). The hernia mesh is a "medical device" that is made out of polypropylene and is marketed "by Defendants as mesh used in

---

[1] The Court accepts the well-pleaded factual allegations in the complaint as true, as is required at this stage. For ease of reference, certain key items from the record will be abbreviated as follows:

DE = docket entry number in this case;

Compl = plaintiff Mills's complaint (DE 1-1);

DABr = defendants' AMC and Maquet motion to dismiss (DE 25);

DGBr = defendant Getinge AB's motion to dismiss (DE 26);

PABr = plaintiff Mills's opposition brief to AMC and Maquet's motion (DE 29);

PGBr = plaintiff Mills's opposition brief to Getinge AB's motion (DE 30).

repairing hernias and chest wall defects." (Compl ¶¶44-46). Hernia meshes are designed and are used for permanent implantation in the human body. (Compl ¶48).

In November of 2015, Mills was admitted to the hospital for repair of a recurrent ventral hernia. At that time, "it was revealed that she had developed a seroma, and that the mesh had adhered to her bowels." (Compl ¶37). Mills claims that had the hernia mesh device "not failed, she would not have suffered a recurrence of her hernia, adhesions and seroma." (Compl ¶38).

Mills alleges that the hernia mesh device "was designed and is manufactured and distributed by the Defendants, who own the patent on the device that was inserted into Plaintiff's body." (Compl ¶41). Mills claims that "a substantial body of scientific evidence" shows that the polypropylene mesh "is biologically incompatible with human tissue and promotes an immune response" in a "large subset of the population receiving these products." (Compl ¶46). That immune response degrades the mesh, as well as the surrounding tissue, and can contribute to the "severe adverse reactions to the mesh." (Compl ¶46).

Mills further claims that the suppliers of the polypropylene "cautioned all users in their United States Material Safety Data Sheet" that polypropylene "was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." (Compl ¶49). Mills asserts that the polypropylene mesh is not suited for implantation into the human body "due to its small pore size and weave, high volume of material used, selection of polypropylene resin, and other design features." (Compl ¶52).

Mills claims that the "Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene." Indeed, she says, they marketed the hernia mesh device to the medical community and patients "as safe, effective" and reliable. (Compl ¶¶50, 64). She also claims that "Defendants paid doctors,

surgeons, physicians and/or clinicians to promote the hernia mesh device." (Compl ¶61).

Mills asserts that "Defendants failed to comply with the FDA application and reporting requirements" and that "defendants" misrepresented "and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the hernia mesh device." (Compl ¶¶56, 60). She further claims that the mesh is "unreasonably dangerous, defective, and negligently designed" in a number of ways.[2] (Compl ¶54). A malfunction of the mesh "can lead to nerve entrapment and damage, fistulae formation, and chronic pain." (Compl ¶55).

On November 30, 2017, Mills filed a complaint in New Jersey state court, alleging the following claims: (1) negligence; (2) strict products liability – defective design; (3) strict products liability – failure to warn; (4) breach of an express warranty; (5) breach of an implied warranty for a particular purpose; and (6) breach of an implied warranty of merchantability. On December 5, 2017, the Covidien defendants[3] removed the action to this Court, based on complete diversity. (DE 1).

On December 15, 2017, Mills voluntarily dismissed the following defendants: Ethicon Inc; Johnson & Johnson; C.R. Bard Inc.; Davol Inc.; Covidien, Inc.; Covidien LLC; Covidien PLC; Covidien AG; Sofradim Production; and John Doe Corporations 1-100. (DE 2).

Before the Court are two motions to dismiss the complaint filed by the remaining defendants: (1) AMC and Maquet (DE 25); and (2) Getinge AB (DE 26).

---

2 Some noted defects include: the weave of the mesh produces interstices that allow bacteria to enter and "hide from the host defenses to eliminate them"; polypropylene is "impure" and contains additional compounds that are toxic to human tissue; the mesh degrades and releases toxic compounds; and the hernia mesh is insufficiently porous. (Compl ¶54).

3 Covidien, Inc.; Covidien LLC; Covidien PLC; and Covidien AG.

II. Standard

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *See Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008) (Rule 8 "requires a 'showing' rather than a blanket assertion of an entitlement to relief." (citation omitted)). Thus, the complaint's factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, so that a claim is "plausible on its face." *Twombly*, 550 U.S. at 570; *see also West Run Student Hous. Assocs., LLC v. Huntington Nat. Bank*, 712 F.3d 165, 169 (3d Cir. 2013). That facial-plausibility standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Id.*

Rule 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Animal Science Products, Inc. v. China Minmetals Corp.*, 654 F.3d 462, 469 n.9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *New Jersey Carpenters & the Trustees Thereof v. Tishman Const. Corp. of New Jersey*, 760 F.3d 297, 302 (3d Cir. 2014).

When deciding a motion to dismiss, a court typically does not consider matters outside the pleadings. However, a court may consider documents that are "integral to or explicitly relied upon in the complaint" or any "undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *In re Rockefeller*

Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir. 1999) (emphasis and citations omitted); *see In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.7 (3d Cir. 2016); *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (on motion to dismiss, court may consider, *inter alia*, "exhibits attached to the complaint"); *Arcand v. Brother Int'l Corp.*, 673 F. Supp. 2d 282, 292 (D.N.J. 2009) (court may consider documents referenced in complaint that are essential to plaintiff's claim).

Reliance on these types of documents does not convert a motion to dismiss into a motion for summary judgment. "When a complaint relies on a document . . . the plaintiff obviously is on notice of the contents the document, and the need for a chance to refute evidence is greatly diminished." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993).

III. Choice of Law

Mills, AMC, and Maquet all agree that Pennsylvania law applies to Mills's claims. (PABr at 7; DABr at 4-8). Getinge AB does not address the issue. (*See generally* DGBr). AMC and Maquet suggest that New Jersey could apply to this action, as this litigation was filed in New Jersey, but they ultimately contend that Pennsylvania law should apply.

As noted above, Mills is a resident of Pennsylvania, and the surgeries took place in Pennsylvania. Mills's injuries also occurred in Pennsylvania. AMC is incorporated under the laws of Delaware. (DE 26-3).[4] Maquet is the "sister corporation" of AMC. (DGBr at 3 n.1). The complaint alleges that Maquet is a New Jersey corporation; the statement of corporate status submitted by Mills

---

[4] Mills's complaint alleges that AMC is organized under the laws of New Hampshire. (Compl ¶17). However, Getinge AB has submitted AMC's corporate status, a publicly available government document from the State of Delaware, showing that AMC was incorporated under Delaware law. (DE 26-3); *see Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (Court may consider matters of public record without converting the motion to dismiss into a motion for summary judgment); *see also In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of federal agency documents published on government website).

in opposition to Getinge AB's motion to dismiss, however, provides that Maquet is a Delaware LLC. (Compl ¶18; DE 30-2). Getinge AB is a Swedish corporation, with a principal place of business in Sweden. (Compl ¶19).

A. Standard

"[I]n a diversity action, a district court must apply the choice of law rules of the forum state to determine what law will govern the substantive issues of a case." *Warriner v. Stanton*, 475 F.3d 497, 499-500 (3d Cir. 2007) (citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941)). New Jersey uses the most-significant-relationship test, which consists of two prongs. *Maniscalco v. Brother Int'l Corp. (USA)*, 793 F. Supp. 2d 696, 704 (D.N.J. 2011), *aff'd*, 709 F.3d 202 (3d Cir. 2013); *see also Yocham v. Novartis Pharm. Corp.*, 736 F. Supp. 2d 875, 880 (D.N.J. 2010) ("Although the New Jersey Supreme Court has not explicitly adopted the Restatement's test for contract claims, New Jersey courts have regularly applied the 'most significant relationship' test to such claims." (citing cases)); *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 461 (D.N.J. 2009) (applying New Jersey's most significant relationship test to tort and breach of contract claims).

First, the court must determine whether a conflict actually exists between the potentially applicable laws. *P.V. v. Camp Jaycee*, 197 N.J. 132, 143 (2008) ("Procedurally, the first step is to determine whether an actual conflict exists. That is done by examining the substance of the potentially applicable laws to determine whether there is a distinction between them.") (internal quotations omitted). "[I]f no conflict exists, the law of the forum state applies." *Snyder v. Farnam Companies, Inc.*, 792 F. Supp. 2d 712, 717 (D.N.J. 2011) (quoting *P.V.*, 197 N.J. at 143). However, if a conflict exists, the court goes to the second step of the analysis and must determine "which state has the 'most significant relationship' to the claim at issue by weighing the factors" in the applicable section of the Restatement (Second) of Conflict of Laws. *Agostino*, 256 F.R.D. at 462; *see also P.V.*, 197 N.J. at 144.

For the tort claims, the Restatement provides that the case will be "determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6." Restatement (Second) of Conflict of Laws, § 145 (1988); *see Yocham*, 736 F. Supp. 2d at 880. Section 146 of the Restatement provides a "default" rule for personal injury cases, and provides that "the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties." Restatement (Second) of Conflict of Laws, § 146 (1988); *Yocham*, 736 F. Supp. 2d at 880 (citing *P.V.*, 197 N.J. at 147).

For contract claims, the applicable Restatement section is § 188. *Gilbert Spruance Co. v. Pennsylvania Mfrs. Ass'n Ins. Co.*, 134 N.J. 96, 102 (1993). "The standard for contract claims is identical [to the § 145 tort standard], except the word 'transaction' is substituted for 'occurrence,' § 188, and there is no similar default rule regarding the location of the injury." *Yocham*, 736 F. Supp. at 880.

Therefore, in determining which substantive law to apply, the evaluation of both the contract and tort claims "involve[s] the significance of the states' relations to the parties and events in light of the principles contained in § 6 of the Restatement, which lists several factors relevant to the choice of law analysis that when 'reduced to their essence . . . are: (1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states." *Yocham*, 736 F. Supp. 2d at 880-81 (alteration added) (citing *P.V.*, 197 N.J. at 148).

B. Actual conflict between Pennsylvania and New Jersey law

The first step of the choice of law analysis requires that the Court determine whether the potentially applicable state laws are in conflict.

In the products liability context, there is a conflict between New Jersey and Pennsylvania law. Unlike Pennsylvania, New Jersey has enacted the New Jersey Product Liability Act ("NJPLA") to codify its products liability law. *Kallman v. Aronchick*, 981 F. Supp. 2d 372, 378 (E.D. Pa. 2013) (citing N.J. Stat. Ann. § 2A:58C-1, *et seq.*). As a result, "Pennsylvania law allows negligence and breach of warranty claims, but New Jersey only allows one statutory cause of action for strict liability." *Torres v. Lucca's Bakery*, 487 F. Supp. 2d 507, 513 (D.N.J. 2007) (citing N.J. Stat. Ann. § 2A:58C-2; *Green v. Gen. Motors Corp.*, 310 N.J. Super. 507, 517 (App. Div. 1998) ("Under the New Jersey Products Liability Act . . . the causes of action for negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action, the essence of which is strict liability."); *Oquendo v. Bettcher Indust.*, 939 F. Supp. 357, 361 (D.N.J. 1996); 13 Pa. Cons. Stat. §§ 2314, 2315 (creating causes of action for breach of implied warranties); *Soufflas v. Zimmer*, 474 F. Supp. 2d 737, 751-54 (E.D. Pa. 2007) (discussing product liability claims based on implied warranties and negligence under Pennsylvania law)); *see also Kallman*, 981 F. Supp. at 378 (noting that NJPLA "subsumes common law products liability claims into one statutory cause of action for strict liability."). In addition, Pennsylvania bars strict liability claims that are brought for injuries related to a medical device, while New Jersey does not. *See* Section IV, A, *infra.*

The NJPLA is the "sole basis of relief under New Jersey law available to consumers injured by a defective product." *Repola v. Morbark Industries, Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). The NJPLA, therefore, does not permit negligence or implied breach of warranty claims as separate claims for injuries caused by defective products.[5] *Kallman*, 981 F. Supp. at 378 (citing *Torres*, 487

---

5 That statute appears to carve out an exception for a claim for breach of an express warranty. *See* N.J. Stat. Ann. §2A:58C-1(b)(3) ("'Product liability action' means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.").

F. Supp. 2d at 513); *see also Knipe v. Smithkline Beecham*, 583 F. Supp. 2d 602, 614 (E.D. Pa. 2008) ("Pennsylvania courts allow claims of negligence and breach of implied warranty to be brought in conjunction with a products liability claim."); *Borelli v. Everland*, 2006 U.S. Dist. LEXIS 6506, at *9 (E.D. Pa. Feb. 21, 2006) ("[U]nder the NJPLA, negligence and breach of warranty are not permitted as separate claims for injuries caused by defective products." (citations omitted)).

Additionally, "New Jersey applies a reasonableness standard to the manufacturer's design in strict liability cases and insulates a non-manufacturing seller from liability, where Pennsylvania does not." *Coppola v. Ferrellgas*, 250 F.R.D. 195, 202 (E.D. Pa. 2008) (citation omitted); *see also* N.J. Stat. Ann. § 2A:58C-9(b) ("Upon filing the affidavit . . . the product seller shall be relieved of all strict liability claims.").

"When dealing with liability based on negligence, strict liability, products liability or the like, differing rules as to liability or damages generally represent genuine conflicts since the laws covering these issues take into account both the needs of the injured plaintiffs and the economic viability of the defendants." *Torres*, 487 F. Supp. 2d at 513 (internal quotation omitted) (citing *Boyes v. Greenwich Boat Works, Inc.*, 27 F. Supp. 2d 543, 548 (D.N.J. 1998)).

When two states authorize different causes of action arising out of the same set of facts, a conflict exists between the laws of the two states. *See Torres*, 487 F. Supp. 2d at 513. I therefore conclude that a conflict exists between the products liability laws of New Jersey and Pennsylvania and turn to the second step of the choice of law analysis. *See Kallman*, 981 F. Supp. 2d at 379 (concluding that conflict exists between products liability laws of Pennsylvania and New Jersey); *Knipe*, 583 F. Supp. 2d at 614 (holding same); *Torres*, 487 F. Supp. 2d at 513 (holding same).

C. Most significant relationship

The policies underlying products liability law in New Jersey and Pennsylvania "are generally the same: both states seek to compensate people

injured by defective products and regulate the conduct of manufacturers and distributors (i.e., ensure production of safe products) within the state." *Torres*, 487 F. Supp. 2d at 513. Each of the states' respective interests would therefore be impaired by the application of the other state's law. Because the policies are in equipoise, the quality of each state's contacts to the underlying action is determinative.

The quality of the contacts with Pennsylvania leads the Court to conclude that Pennsylvania law should apply. In making this determination, the Court must look to a number of factors: "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." Restatement (Second) of Conflict of Laws § 145 (1988); *see also Knipe*, 583 F. Supp. 2d at 614.

The events essential to this litigation occurred in Pennsylvania. Mills is a resident of Pennsylvania, and the allegedly defective product was used and caused harm in the state of Pennsylvania. Mills's surgeries, during which the product was implanted, also occurred in Pennsylvania. Only Maquet, which is incorporated in this state, has a connection to New Jersey. *See Knipe*, 583 F. Supp. 2d at 616 (applying New Jersey law where "[t]he sole contact Pennsylvania maintains with this litigation is as the situs of Defendant's headquarters and principal place of business.").

New Jersey has a tenuous connection to the harm caused to Mills, and therefore has little interest in having its products liability law enforced to protect the rights and interests of a non-resident. *See Deemer v. Silk City Textile Mach. Co.*, 193 N.J. Super. 643, 649 (App. Div. 1984) ("New Jersey has no interest in protecting the compensation rights of a non-domiciliary resident. Indeed, our Supreme Court . . . appears to evidence a policy of discouraging forum shopping where, as here, the contacts with the State are at best

tenuous." (citations omitted)). Accordingly, I conclude that Pennsylvania law applies to the substantive claims in this action.

IV. Discussion

The complaint contains six counts:

Count One: Negligence;

Count Two: Strict Products Liability – Defective Design;

Count Three: Strict Products Liability – Failure to Warn;

Count Four: Breach of Express Warranties;

Count Five: Breach of Implied Warranty of Fitness for Particular Purpose;

Count Six: Breach of Implied Warranty of Merchantability.

A. Viability of Causes of Action under Pennsylvania law

Before addressing the sufficiency of the factual allegations in the complaint, I consider which causes of action are viable under Pennsylvania law. Maquet and AMC argue that Pennsylvania law does not recognize products liability claims for strict liability or breach of warranty relating to a medical device.

This Court's "role in diversity cases is to apply state law as announced by the state's highest court." *LaBarre v. Bristol-Myers Squibb Co.*, 544 F. App'x 120, 125 (3d Cir. 2013) (citing *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 253 (3d Cir. 2010) ("A federal court under *Erie* is bound to follow state law as announced by the highest state court." (internal citations omitted)). "In the absence of a controlling decision by the Pennsylvania Supreme Court, we must predict how it would decide the questions of law presented in this case." *Wolfe v. Allstate Prop. & Cas. Ins. Co.*, 790 F.3d 487, 492 (3d Cir. 2015) (citing *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45-46 (3d Cir. 2009)); *Leonard v. Tractor Supply Co.*, 88 F. Supp. 3d 459, 461 (W.D. Pa. 2015). A federal district court in this position should consider "relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *Berrier*, 563 F.3d at 46 (quotation and citation omitted).

i. Strict liability claims

The second count of Mills's complaint alleges strict liability based on defective design, and the third count alleges strict liability based on a failure to warn. As many courts have recognized, the Pennsylvania Supreme Court has not yet decided whether Pennsylvania law recognizes strict liability claims related to medical devices. That court has, however, barred such claims in the analogous context of prescription medications. For the reasons stated below, I think it would apply those precedents to medical devices as well.

Pennsylvania has adopted the strict liability formulation set out in Section 402A of the Restatement (Second) of Torts. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014); *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966). Pennsylvania law recognizes three different types of defects that can give rise to a strict-liability claim: (1) design defect; (2) manufacturing defect; and (3) warning defect (i.e., failure to warn or inadequate warnings). *See Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995); *Doughtery v. C.R. Bard*, 2012 U.S. Dist. LEXIS 100374, at *4-6 (E.D. Pa. July 18, 2012).

In *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996), the Pennsylvania Supreme Court adopted Comment k to Section 402A of the Restatement to bar strict liability claims where a prescription drug is at issue. Comment k limits liability for "[u]navoidably unsafe products" and provides as follows:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental

> drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis in original).

In *Hahn*, the Pennsylvania Supreme Court therefore held that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Hahn*, 673 A.2d at 891. The lower court opinion in *Hahn* explained that prescription drugs are both inherently dangerous and greatly beneficial to society. *Hahn v. Richter*, 628 A.2d 860, 871 (Pa. Super. Ct. 1993), *aff'd*, 673 A.2d 888 (Pa. 1996). To hold manufacturers of prescription drugs liable for "unforeseeable reactions to their products . . . would stifle the incentive to produce new products." *Id.*

The Pennsylvania Supreme Court more recently reaffirmed that Comment k bars strict liability for prescription drug manufacturers in *Lance v. Wyeth*, 85 A.3d 434, 438 (Pa. 2014). Pennsylvania courts have also specifically applied Comment k to bar strict liability theories based on a failure-to-warn as well as a design defect theory. *See Hahn*, 673 A.2d at 891 (applying Comment k to failure-to-warn claim); *Lance v. Wyeth*, 4 A.3d 160, 165 (Pa. Super. Ct. 2010) ("With our Supreme Court's adoption of comment k, a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs."), *rev'd in part on other grounds*, 85 A.3d 434 (Pa. 2014); *see also Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971) (observing that Pennsylvania law does not impose strict liability on prescription drugs "merely because of dangerous propensities of the product.");

Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984) ("[A] manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk.").

As noted by Mills, however, Comment k speaks in terms of prescription drugs; it does not specifically mention medical devices. Although the Pennsylvania Supreme Court has not yet addressed the distinction, Pennsylvania's intermediate appellate court has explained that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (alteration added) (affirming trial court determination that plaintiffs' strict liability claim for medical device was barred by Comment k).[6] The court in *Creazzo* also rejected the plaintiffs' argument that Comment k should not apply "to medical devices because the comment text does not mention them." *Id.* The Court reasoned that there was no authority "for so restrictive an interpretation either of comment k or of *Hahn*." *Id.*

Federal courts, faced with the same issue of Pennsylvania law, have unanimously held that Comment k applies to medical devices, barring strict liability design defect and failure-to-warn claims. *See, e.g., Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 848 (E.D. Pa. 2017) (dismissing strict liability design defect claim related to medical device); *Carson v. Atrium Med. Corp.*, 191 F. Supp. 3d 473, 477 (W.D. Pa. 2016) (dismissing plaintiff's strict liability failure to warn claim related to polypropylene hernia mesh); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833 (E.D. Pa. 2016) (concluding that "Comment k's prohibition of strict liability-design defect and strict liability-failure to warn claims for prescription drugs should also apply to

---

6 The device at issue was "known as the Model 7425 Itrel 3 Implantable Neurological Electrical Pulse Generator (the Itrel 3)" and "was designed to alleviate chronic pain by passing an electrical stimulus through nerve structures in the dorsal aspect of the patient's spinal cord by way of a stimulation lead." *Creazzo*, 903 A.2d at 26.

medical devices."); *Runner v. C.R. Bard, Inc.*, 108 F. Supp. 3d 261, 266 (E.D. Pa. 2015) (dismissing plaintiff's strict liability claims relating to mesh based on Comment k); *Kee v. Zimmer*, Inc., 871 F. Supp. 2d 405, 410 (E.D. Pa. 2012) (dismissing strict liability failure to warn claim related to medical device); *McPhee v. Depuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 461 (W.D. Pa. 2012) (dismissing strict liability failure to warn claim and design defect claims pursuant to Comment k); *Soufflas*, 474 F. Supp. 2d at 750 (dismissing design and failure to warn strict liability claims and predicting that Pennsylvania Supreme Court would adopt Comment k to medical devices); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (dismissing strict liability design and failure to warn claims); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004) ("Comment k precludes application of Section 402A to prescription medical devices.").[7]

---

[7] *See also Atkinson v. Ethicon, Inc.*, 2019 U.S. Dist. LEXIS 115224, at *12 (W.D. Pa. July 11, 2019) (determining that strict liability failure to warn and design defect claims were barred by Pennsylvania law); *Buck v. Endo Pharm., Inc.*, 2019 U.S. Dist. LEXIS 71974, at *20 (E.D. Pa. Apr. 29, 2019) (concluding that "strict liability design defect and failure to warn claims under Pennsylvania law fail."); *Wallace v. Bos. Sci. Corp.*, 2018 U.S. Dist. LEXIS 203441, at *16-17 (M.D. Pa. Nov. 29, 2018), *R&R adopted by*, 2019 U.S. Dist. LEXIS 3434 (M.D. Pa. Jan. 8, 2019) (dismissing strict liability design defect and failure to warn claims related to implantation of mesh device); *Krammes v. Zimmer, Inc.*, 2015 U.S. Dist. LEXIS 96954, at *12 (M.D. Pa. July 24, 2015) (predicting Pennsylvania Supreme Court would adopt Comment k to medical devices and dismissing strict liability design defect claim); *Cogswell v. Wright Med. Tech., Inc.*, 2015 U.S. Dist. LEXIS 92461, at *9 (W.D. Pa. July 16, 2015) (barring strict liability failure to warn claim related to medical device); *Shelley v. Ethicon, Inc.*, 2013 U.S. Dist. LEXIS 95981, at *6 (E.D. Pa. July 9, 2013) (dismissing strict liability failure to warn claim related to implantation of surgical mesh); *Kline v. Zimmer Holdings, Inc.*, 2013 U.S. Dist. LEXIS 91340, at *15 (W.D. Pa. May 31, 2013) (dismissing design defect and failure to warn claims); *Tatum v. Takeda Pharm. N. Am., Inc.*, 2012 U.S. Dist. LEXIS 151031, at *5 (E.D. Pa. Oct. 18, 2012) (concluding that "strict liability based on design defect and strict liability based on failure to warn are not permitted under Pennsylvania law"); *Doughtery v. C.R. Bard*, 2012 U.S. Dist. LEXIS 100374, at *25 (E.D. Pa. July 18, 2012) ("Doughtery's strict-liability claims based on a design defect and a failure-to-warn . . . are not cognizable under Pennsylvania law."); *Horsmon v. Zimmer Holdings, Inc.*, 2011 U.S. Dist. LEXIS 130415, at *6 (W.D. Pa. Nov. 10, 2011) (holding that medical device "claim for strict liability is precluded by Pennsylvania law.").

Likewise, every federal district court to confront this issue has predicted that the Pennsylvania Supreme Court would extend Comment k's application to strict liability design defect and failure to warn claims related to medical devices. *Rosenberg v. C.R. Bard, Inc.*, 2019 U.S. Dist. LEXIS 105785, at *9 (E.D. Pa. June 25, 2019).[8] While I am not bound by those cases, I agree with them, and am persuaded by the analysis of the Pennsylvania Superior Court in *Creazzo*. The language in Comment k is not strictly limited; it applies to "other drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." Like prescription drugs, medical devices generally are sold through a physician, are directed to the treatment of medical conditions, and have unquestioned benefits that may outweigh the risk of potential harm.[9] The Pennsylvania Supreme Court would

---

8 There is some division among federal courts as to whether a claim for strict liability based on a manufacturing defect, a claim Mills has not pled, would also be barred. *See Cogswell*, 2015 U.S. Dist. LEXIS 92461, at *7 ("There is currently a split among federal district courts applying Pennsylvania law on the application of strict liability to manufacturing defect claims."); *Atkinson*, 2019 U.S. Dist. LEXIS 115224, at *12 ("As to strict liability, there is a split among federal district courts applying Pennsylvania law as to whether strict liability is an available cause of action against the manufacturer of a medical device; yet, even under the most permissive interpretation, such claims exist only with respect to manufacturing defects in medical devices and not with respect to other theories of strict liability."). The Court in *Rosenberg*, recognizing that courts were divided as to whether a strict liability manufacturing defect is a viable claim under Pennsylvania law, certified the question to the Third Circuit. *Rosenberg*, 2019 U.S. Dist. LEXIS 105785, at *20. However, neither party in that case made an application to the Third Circuit and the certification was dismissed as moot. *Rosenberg v. C.R. Bard, Inc.*, Civ. No. 18-4767 (Aug. 12, 2019) (Order) (DE 30). Since that claim is not pled in Mills's complaint, I do not address that issue.

9 Mills suggests that the mesh product is not an "unavoidably unsafe" product under Comment k. The Pennsylvania District Court cases cited above, however, have taken a more categorical approach, reasoning that medical devices in general fall under the umbrella of Comment k and rejecting a device-by-device analysis. *Carson*, 191 F. Supp. 3d at 477 ("Plaintiff's argument that exceptions be made is unpersuasive, and the Court will apply Comment k, without exceptions, to medical devices."); *Kee*, 871 F. Supp. 2d at 410 ("Even assuming that Plaintiff's argument that a case-by-case analysis is a 'better course of action,' this is not the law in Pennsylvania. . . . And a federal court in a diversity action is not free to enforce its policy predilections at the expense of state law."); *see also Cogswell*, 2015 U.S. Dist. LEXIS 92461, at *12; *Horsmon*, 2011 U.S. Dist. LEXIS 130415, at *6 ("While other jurisdictions might recognize caveats to Comment k's exclusion of strict liability

likely hold that, for policy reasons and as a matter of logic, these arguments apply equally to prescription drugs and medical devices.

Mills fails to cite any case law allowing either a strict liability design defect or failure to warn claim to proceed under Pennsylvania law with respect to a medical device. Mills cites the Pennsylvania Supreme Court's recent decision in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 382 (Pa. 2014) for the broad proposition that "[n]o product is expressly exempt" from strict liability. In *Tincher*, homeowners brought an action against the manufacturer of stainless-steel tubing. 104 A.3d at 335-36. Notably, *Tincher* is not a prescription drug or medical device case, and the Court did not overrule *Hahn* or *Lance*, even though the opinion expressly overruled another Pennsylvania Supreme Court opinion, *Azzarello v. Black Brothers Co.*, 391 A.2d 1020 (Pa. 1978).

Additionally, the Pennsylvania Supreme Court specifically noted an exception in *Tincher* to this general proposition, by immediately following this broad statement with a "but see" citation to *Hahn*, signaling that "where adequacy of warnings associated with prescription drugs is at issue, strict liability is not recognized as basis for liability." *Id.* at 362 n.13; *see also In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, 2015 WL 3669933, at *35 (N.D. Ill. June 12, 2015) ("*Tincher* acknowledged *Hahn*'s holding that strict liability is unavailable for prescription drug claims premised on defective design or inadequate warning, *see id.*, but the Court declined to categorically bar strict liability claims for any other types of products, even 'innovative products with no comparable alternative design[.]'").

Absent more specific contrary guidance from the Pennsylvania Supreme Court, this Court concludes that Mills's strict liability claims are not viable. Like every court before me, I conclude that Pennsylvania law bars Mills's strict liability design defect and failure-to-warn claims regarding this medical device.

---

claims, this Court must apply Pennsylvania law, which does not recognize such caveats.").

Counts two and three are therefore dismissed. Because amending the complaint would be futile, this dismissal is with prejudice.

ii. Implied warranty claims

Defendants argue that Mills's claims for breach of an implied warranty for a particular purpose and of merchantability (the fifth and sixth counts of the complaint) are also barred under Pennsylvania law. Mills simply argues that Pennsylvania Supreme Court has not yet so ruled, and that therefore she should be allowed to proceed with these implied warranty claims. (PABr at 17).

"The implied warranty of merchantability and fitness for particular purpose arise by operation of law and were created to protected buyers from products sold below commercial standards or unfit for the buyer's purposes." *Soufflas*, 474 F. Supp. 2d at 751 (citing *Altronics of Bethlehem, Inc. v. Repco, Inc.*, 957 F.2d 1102, 1105 (3d Cir. 1992)).

The implied warranty of merchantability "'serve[s] to protect buyers from loss where goods purchased are below commercial standards.'" *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *26 (quoting *Turney Media Fuel, Inc. v. Toll Bros., Inc.*, 725 A.2d 836, 840 (Pa. Super. Ct. 1999)); *see also* 13 Pa. Cons. Stat. Ann. § 2314(a). "The essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used." *Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 376 (Pa. Super. Ct. 1987) (citing *Wisniewski v. Great Atl. & Pac. Tea Co.*, 323 A.2d 744, 746-47 (Pa. Super. Ct. 1974); Pa. Cons. Stat. Ann. § 2314(b)(3)).[10]

Under § 2314(a), "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." In order to meet the definition of "merchantable," products must be "fit for the ordinary purpose for which such goods are used." 13 Pa. Cons. Stat. Ann. § 2314(b)(3).

---

10 For clarity, I note that here and throughout, "13 Pa. Cons. Stat. Ann. § 2___" refers to Article 2 of Pennsylvania's version of the Uniform Commercial Code. Thus, for example, 13 Pa. Cons. Stat. Ann. § 2314 corresponds to UCC 2-314.

"[W]hereas the implied warranty of merchantability 'is based on the seller's implicit representation that the product will safely and effectively perform the normal functions for which that type of product is ordinarily bought and sold,' the implied warranty of fitness for a particular purpose 'is an implied promise by the seller that the product sold will meet the buyer's particular needs." *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *31 (quoting 1 Madden & Owen on Products Liability § 4:8, at 154); *see* 13 Pa. Cons. Stat. Ann. § 2314(b)(3). This implied warranty of fitness "is 'based upon a special reliance by the buyer on the seller to provide goods that will perform a specific use envisaged and communicated by the buyer.'" *Id.* (citation omitted). Breach of the implied warranty of fitness for a particular purpose does not require a defective product; rather, "this warranty 'may be breached when a product properly made and merchantable is simply the wrong one for the buyer's particular use.'" *Id.* (quoting 1 Madden Owen on Products Liability § 4:8, at 162).

In *Makripodis*, the plaintiff asserted claims for breach of the implied warranty of merchantability and for strict liability against the manufacturer of a prescription drug. 523 A.2d at 375. The plaintiff claimed that she ingested the drug during pregnancy, and that it caused congenital abnormalities to her child. *Id.* The novel issue presented in that case was whether "a retail druggist, who properly fills a prescription of a medical doctor with the proper and unadulterated drug prescribed, is liable to the patient-purchaser for breach of an implied warranty of merchantability if the drug produces harmful effects upon the purchaser." *Id.* at 376.

Relying on Comment k in the Restatement (Second) of Torts, the court granted summary judgment on both of plaintiff's claims. It dismissed the breach of implied warranty of merchantability on the following grounds:

> The essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used . . . [T]he very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for "ordinary purposes," as each individual for whom they are prescribed is a unique organism

> who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient.

Id. at 376-77 (alteration added).[11]

Although the Pennsylvania Supreme Court has not yet ruled on this specific question, many federal courts have followed *Makripodis* and dismissed implied warranty of merchantability claims with respect to medical devices. Essentially, those cases apply the same logic that served to preclude strict liability claims. *See Carson*, 191 F. Supp. 3d at 478 ("Since this Court has determined, both in this case and in previous cases, that medical devices fall under the umbrella of Comment k, and thus are unavoidably unsafe products, there can be no breach of implied warranty."); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 491 n.34 (W.D. Pa. 2012) (relying on *Makripodis* and concluding that Pennsylvania law does not recognize breach of warranty claim for medical device); *McPhee*, 989 F. Supp. 2d at 464 (concluding that implied warranty claims for merchantability and fitness for a particular purpose were barred under Pennsylvania state law); *Kee*, 871 F. Supp. 2d at 409 n.3 (granting motion to dismiss implied warranty claim arising from medical device implanted during knee surgery); *Soufflas*, 474 F. Supp. 2d at 751 ("Like Plaintiff's strict liability claims, summary judgment in favor of Defendant is also warranted with respect to Plaintiff's implied warranty of merchantability and fitness for a particular purpose claims."); *Parkinson*, 315 F. Supp. 2d at

---

[11] The court held that a pharmacist who dispenses a medication prescribed by a licensed physician "only warrants" the following:

> (1) that he has compounded the drug prescribed with due care,
>
> (2) in the strength and quantity prescribed,
>
> (3) that he has used the proper methods in the compounding process,
>
> (4) that the drug is pure and unadulterated, and
>
> (5) that he has labeled the drug in accordance with the directives of the physician's prescription.

Makripodis, 523 A.2d at 377.

753 (dismissing claims for breach of implied warranties of merchantability and of fitness for particular purpose because "[a]s breach of implied warranty claims for prescription drugs are precluded under Pennsylvania law, breach of implied warranty claims for prescription medical devices also are precluded for identical reasons."); *Davenport*, 302 F. Supp. 2d at 442 ("Similar to the reasoning in *Hahn* relating to application of Section 402A, 'Pennsylvania courts have held that the nature of prescription drugs also precludes claims for breach of the implied warranty of merchantability.'").[12]

The logic is sound. Strict liability and breach of an implied warranty "are parallel theories of recovery, one in contract and the other in tort." *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *29 (citations omitted); *accord Williams v. West Penn Power Co.*, 467 A.2d 811, 815 n.16 (Pa. 1983) (indicating that strict liability claims addressed by Restatement § 402A and breach of the implied warranty of merchantability addressed by the Uniform Commercial Code are "co-extensive"). "[A] breach of implied warranty theory is a form of strict liability

---

12 *See also Terrell v. Davol, Inc.*, 2014 U.S. Dist. LEXIS 103695, at *24 (E.D. Pa. July 30, 2014) (dismissing breach of implied warranty of merchantability and fitness for a particular purpose claims related to hernia mesh because "[t]he same reasons discussed above that preclude strict liability claims involving medical devices would apply to breach of implied warranty of merchantability claims."); *Killen v. Stryker Spine*, 2012 U.S. Dist. LEXIS 140476, at *11 (W.D. Pa. Sep. 28, 2012) (dismissing implied warranty of merchantability claim related to medical device); *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *28-29 ("I agree with these courts insofar as they held that comment k precludes implied-warranty claims against manufacturers of prescription drugs and devices to the same extent that it precludes strict-liability claims against such manufacturers."); *Horsmon*, 2011 U.S. Dist. LEXIS 130415, at 7 ("Several courts have extended the reasoning of *Makripodis* to preclude claims against medical device manufacturers for breach of implied warranties of merchantability and fitness for a particular purpose" and dismissing those claims); *Kester v. Zimmer Holdings, Inc.*, 2010 U.S. Dist. LEXIS 59869, at 31-33 (W.D. Pa. June 16, 2010) ("As with strict products liability claims . . . , Pennsylvania courts have held that the nature of prescription drugs and prescription medical devices precludes claims for breach of implied warranty."); *Murray v. Synthes (U.S.A.), Inc.*, 1999 U.S. Dist. LEXIS 13436, at *28 (E.D. Pa. Aug. 23, 1999) (recognizing that *Makripodis* bars breach of implied warranty claims based on medical devices); *Taylor v. Danek Med., Inc.*, 1998 U.S. Dist. LEXIS 20265, at *40 (E.D. Pa. Dec. 29, 1998) ("Because Pennsylvania does not recognize strict liability claims for prescription medical products . . . this Court predicts that the Pennsylvania Supreme Court would exclude a cause of action based on the implied warranty of merchantability for prescription medical devices.").

without the necessity of proving negligence or fault on the part of the defendant." *Id.* (citing *Kassab v. Central Soya*, 246 A.2d 848, 853 (Pa. 1968) ("[O]nce a breach of warranty has been shown, the defendant's liability, assuming of course the presence of proximate cause and damages, is absolute. Lack of negligence on the seller's part is no defense."), *overruled on other grounds by, AM/PM Franchise Ass'n v. Atlantic Richfield Co.*, 584 A.2d 915 (Pa. 1990)). As one court explained, it would "be inconsistent to exempt a manufacturer of prescription medical devices from strict liability under comment k and apply a negligence standard to determine liability for a design defect or a failure to warn, but allow a plaintiff to recover for the same alleged defect under a theory of breach of the implied warranty of merchantability." *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *30.

Mills has not cited any cases that have permitted an implied breach of warranty claim to proceed in relation to a prescription medical device or offered any reason to distinguish these cases. Therefore, the Court will dismiss the fifth and sixth counts of the complaint with prejudice.

iii. Express warranty claim

Next, defendants argue that Mills's express warranty claim (the fourth count of the complaint) is also barred by *Hahn* and Comment k. Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. Ann. § 2313(a).

Federal courts are split on the viability of an express warranty claim for a medical device under Pennsylvania law. *Cogswell*, 2015 U.S. Dist. LEXIS 92461, at *10. Some courts have recognized an express-warranty cause of action, "albeit without discussing whether comment k precludes such a claim." *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *33-34 (citing *Kee*, 871 F. Supp. 2d 405, 410-11; *Horsmon*, 2011 U.S. Dist. LEXIS 130415, at *10-14; *Esposito v. I-Flow Corp.*, 2011 U.S. Dist. LEXIS 122570, at *18-21 (E.D. Pa. Oct. 18,

2011); *Kester*, 2010 U.S. Dist. LEXIS 59869, at *27-31; *Parkinson*, 315 F. Supp. 2d at 751-52; *Davenport*, 302 F. Supp. 2d at 440-41).

Other courts, directly addressing the medical-device issue, "have barred express warranty claims, relying on the statement in *Hahn* that 'where the adequacy of warnings associated with prescription drugs is at issue [the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e.,] the manufacturer's negligence, is the *only recognized basis of liability.*'" *Cogswell*, 2015 U.S. Dist. LEXIS 92461, at *10 (quoting *Hahn*, 673 A.2d at 891) (alteration and emphasis added); *see Carson*, 191 F. Supp. 3d at 479 (dismissing breach of express warranty under *Hahn*); *Rowland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 556, 569 (W.D. Pa. 2014) ("Courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs."); *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 755 (W.D. Pa. 2011) ("[T]he Supreme Court of Pennsylvania has ruled that a pharmaceutical manufacturer cannot be held liable for a claim that is not based in negligence." (alteration added)); *Aaron v. Wyeth*, 2010 WL 653984, at *11 (W.D. Pa. Feb. 19, 2010) (dismissing express warranty claim because "*Hahn* requires that this Court dismiss all claims that do not rest on a theory of negligence."); *Leonard v. Taro Pharm. USA, Inc.*, 2010 U.S. Dist. LEXIS 127892, at *13 (W.D. Pa. Dec. 2, 2010) ("In light of *Hahn* and its progeny, this Court will grant defendant's Motion to Dismiss Plaintiff's breach of express warranty . . . and breach of implied warranty."); *Kline v. Pfizer, Inc.*, 2008 WL 4787577 *4 (E.D. Pa. 2008) (dismissing breach of express and implied warranty claims, fraudulent misrepresentation, fraudulent concealment, and unjust enrichment claims under *Hahn*); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 548 (E.D. Pa. 2006) (dismissing breach of implied warranty, fraud by intentional misrepresentation, intentional infliction of emotional distress, and strict liability claims under *Hahn*), *rev'd on other grounds*, 521 F.3d 253 (3d Cir. 2008).

I am not persuaded that the Pennsylvania Supreme Court's statement should be stretched to bar all non-negligence claims. *Hahn* specifically addressed a failure-to-warn claim and determined that such a claim could not proceed on a theory of strict liability. 673 A.2d at 891. *Hahn* did not decide whether a breach of express warranty claim could proceed. The court's statement that negligence was "the only recognized basis of liability" was clearly related to its analysis of a strict liability failure to warn claim.[13]

"Unlike an implied warranty, which arises by operation of law, an express warranty is based on express representations or promises made by the seller." *Doughtery*, 2012 U.S. Dist. LEXIS 100374, at *34 (citing 13 Pa. Cons. Stat. Ann. § 2313). "A claim for breach of express warranty thus sounds more in contract than in tort." *Id.* At least one district court has determined that while the reasoning underlying the purpose of Comment k "may prevent certain warranties or promises from being implied by law," there is "no basis for declining to enforce a contractual promise expressly and voluntarily made by a manufacturer of prescription drugs or devices." *Id.*; *see Shelley v. Ethicon, Inc.*, 2013 U.S. Dist. LEXIS 95981, at *6 (E.D. Pa. July 9, 2013) (concluding that breach of express warranty claims is viable under Pennsylvania law); *Killen*, 2012 U.S. Dist. LEXIS 140476, at *13 (determining that "Pennsylvania law does not preclude express warranty claims against manufacturers of prescription drugs and devices.").

Thus, the Court concludes that a claim for breach of express warranty is not categorically barred as a matter of Pennsylvania law. Count four, the express warranty claim, will not be dismissed on this basis.

B. Sufficiency of the pleading

Defendants also argue that the remaining claims in the complaint—*i.e.*, negligence (count one) and express warranty (count four) fail to meet the

---

13 The highest court later emphasized that *Hahn* only addressed whether a failure to warn claim could be premised upon a theory of strict liability and did not address causes of action under a warranty theory. *See Lance*, 85 A.3d at 465 n.8 (explaining that strict liability is merely a subset of products liability law).

pleading standards for stating a claim under Rule 12(b)(6).[14] On this point, defendants raise a series of issues. They argue that the complaint fails to identify the defective product or its manufacturer, and that Mills has engaged in improper group pleading, asserting her "claims generally against all Defendants in a conclusory and boilerplate fashion." Defendants also contend that Mills has failed to sufficiently plead warning causation, and that the negligent design claim does not allege that there existed an alternative, safer design. (DABr at 9-11). As to the negligent failure to warn claim, defendants cite the learned intermediary doctrine. As to the express warranty claim, defendants argue that the complaint fails to plead notice or the existence of an "affirmation." (DABr at 11, 16).

i. Negligence claim

Count one, the negligence claim, alleges that "Defendants were regularly engaged in the business of designing . . . manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling medical devices known as hernia mesh devices." (Compl ¶80). The complaint alleges that "Defendants owed a duty to design, research, develop, test, manufacture, package, label. Market, promote, distribute, sell and/or supply products . . . in such a way as to avoid harm." (Compl ¶81).

Count one alleges that "Defendants" negligently manufactured, designed, labeled, marketed, and sold the hernia mesh device. (Compl ¶82). "Despite the fact that Defendants knew or should have known that their hernia mesh devices were associated with and/or causes significant bowel constriction, Defendants continued to market, manufacture, distribute, and/or make available their hernia mesh devices to patients through their surgeons and/or health facilities, including the Plaintiff and her surgeon." (Compl ¶83).

---

[14] Because I conclude that the strict liability and implied warranty claims are not viable under Pennsylvania law, I do not address the sufficiency of the pleading as it relates to them.

Count one alleges a claim for negligent failure to warn, in that "Defendants" failed to "adequately warn of the actual potential of their hernia mesh devices to be harmful to humans" and to warn "of the actual potential for adhesion and bowel constriction when using hernia mesh devices for hernia repair surgery." (Compl ¶82). In terms of causation, the complaint alleges that the "Defendants' negligence . . . was the cause of and substantial factor in bring about Plaintiff's injuries, harm and economic loss." (Compl ¶86).

"Under Pennsylvania law, 'a cause of action for negligence must fail unless defendant's conduct is shown to have been the . . . cause of plaintiff[']s injury." *Kester*, 2010 U.S. Dist. LEXIS 59869, at *17 (quoting *Long v. Krueger, Inc.*, 686 F. Supp. 514, 517 (E.D. Pa. 1988)). "[A]bsent such identification, there can be no allegations of duty, breach of duty or legal causation, and hence there can be no liability." *Id.* (alteration added) (citing *Cummins v. Firestone Tire & Rubber Co.*, 495 A.2d 963, 967-968 (Pa. Super. Ct. 1985)).

Both sides principally discuss *Kester*, 2010 U.S. Dist. LEXIS 59869, at *16-17, so I will briefly address that case. Like Mills, the plaintiff in *Kester* collectively referred to the defendants as the manufacturer and/or the distributor. The Court dismissed plaintiff's negligence claim because the plaintiff did "not adequately identify which of the two 'Defendant Anesthetic Manufacturers' was the manufacturer or distributor of the medication" at issue. *Id.* at *16. The Court reasoned that "the speculative and collective identification of the Defendants fails to adequately identify which Defendant caused Plaintiff's alleged injury and the Complaint, therefore, is insufficient and speculative under *Twombly* and *Iqbal*." *Id.* at *17.

The Court in *Kester* also pointed to "analogous cases" that "held that a plaintiff's generic averments and formulaic recitations fail under the federal pleading standard." *Id.* at *17-18[15] (citations omitted); *see Peterson v. Breg*, 2010 U.S. Dist. LEXIS 48985, at *6 (D. Ariz. Apr. 28, 2010) (dismissing complaint where "Plaintiffs have failed to identify the defendants responsible

---

15 Mills's complaint was originally filed in New Jersey state court.

for manufacturing the pain pump and anesthetic used in their treatment."); *Adams v. I-Flow Corp.*, 2010 U.S. Dist. LEXIS 33066, at *7 (C.D. Cal. Mar. 30, 2010) (dismissing complaint because plaintiff "must allege the identity of the particular defendant who manufactured the pain pump and the particular defendant who manufactured the anesthetic that allegedly injured plaintiff."); *Sherman v. Stryker Corp.*, 2009 U.S. Dist. LEXIS 34105, at *12 (C.D. Cal. Mar. 30, 2009) (dismissing complaint where plaintiff sued "Abbott and AstraZeneca, as manufacturers of pain medication, but conspicuously fails to allege that either manufactured the medication used in the particular pain pump that caused her alleged injury, much less the name or type of medication at issue."); *Dittman v. DJO, LLC*, 2009 U.S. Dist. LEXIS 97106, at *3 (D. Colo. Oct. 5, 2009) (dismissing products liability complaint where plaintiff did "not identify which specific medication was allegedly used during his procedure or directly allege that any of these defendants were the actual manufacturer of the drug that caused his injury.").

Count one of Mills's complaint contains the kind of group pleading that has led courts in this district to dismiss past complaints. This type of pleading fails to satisfy Rule 8 "because it does not place Defendants on notice of the claims against each of them." *Sheeran v. Blyth Shipholding S.A.*, 2015 U.S. Dist. LEXIS 168019, at *8 (D.N.J. Dec. 16, 2015) (citing *Ingris v. Borough of Caldwell*, 2015 WL 3613499, at *5 (D.N.J. June 9, 2015) ("[T]o the extent Plaintiff seeks to lump several defendants together without setting forth what each particular defendant is alleged to have done, he has engaged in impermissibly vague group pleading."); *Shaw v. Hous. Auth. of Camden*, 2012 WL 3283402, at *2 (D.N.J. Aug. 10, 2012) (dismissing complaint because it failed to contain allegations showing how each defendant was liable and noting that "[e]ven under the most liberal notice pleading requirements of Rule 8(a), a plaintiff must differentiate between defendants.")). "Alleging that 'Defendants' undertook certain illegal acts — without more — injects an inherently speculative nature into the pleadings, forcing both the Defendants and the

Court to guess who did what to whom when. Such speculation is anathema to contemporary pleading standards." *Japhet v. Francis E. Parker Mem'l Home, Inc.*, 2014 U.S. Dist. LEXIS 105134, at *7 (D.N.J. July 31, 2014).

It is not clear from Mills's complaint which defendant is the manufacturer or distributor, and the particular legal basis for each claim against each defendant cannot readily be extracted from these catchall allegations. Additionally, the complaint does not assert what *specific* product is at issue—at a minimum, the manufacturer and model of the mesh product should be stated, or a reason should be given if this cannot be done. I will dismiss the negligence count for failure to plead facts in conformity to the standards of *Twombly* and *Iqbal, supra.*

Mills's briefing suggests that amendment would not be futile. The brief asserts that the product at issue is the "ProLite Mesh" and that she has dismissed the defendants that are not part of the chain of distribution for that particular product. "It is one thing," however, "to set forth theories in a brief; it is quite another to make proper allegations in a complaint." *Hughes v. UPS*, 639 F. App'x 99, 104 (3d Cir. 2016) (*quoting Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988)). "It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007) (internal quotation and citation omitted); *see Carpenters Health 86 Welfare Fund of Phila. & Vicinity v. Mgmt. Res. Sys.*, 837 F.3d 378, 383 (3d Cir. 2016) (party may not amend complaint in brief opposing a motion to dismiss).

The general rule in this Circuit is that an initial dismissal for inadequate pleading, like this one, is without prejudice, and I see no reason to depart from that rule. *See Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 236 (3d Cir. 2008);

Alston v. Parker, 363 F.3d 229, 235 (3d Cir. 2004). This dismissal is without prejudice to the submission, within 30 days, of a motion to amend.[16]

ii. Breach of an express warranty

Count four alleges breach of express warranties. Defendants contend that Mills has failed to allege that she notified defendants of any breach, a prerequisite to suit under Pennsylvania law, and that the complaint fails to plead any affirmation of fact or promises made by them.

a. General principles

Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. Ann. § 2313(a). A promise is the "basis of the bargain if the plaintiff can prove 'that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise.'" *Gross*, 858 F. Supp. 2d at 501 (quoting *Parkinson*, 315 F. Supp. 2d at 752).

---

16 I do not address the defendants' remaining arguments on the negligence claim. Nevertheless, for future guidance I make one comment about the learned intermediary doctrine:

> [A] manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be dangerous. The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.

Gurley v. Janssen Pharms., Inc., 113 A.3d 283, 292-93 (Pa. Super. Ct. 2015) (quoting *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676 (Pa. Super. Ct. 2010)). In the motion to dismiss context, if a plaintiff alleges that the manufacturer failed to disclose dangers related to a product to the plaintiff's physician, then the learned intermediary doctrine will not bar that claim from going forward. *See e.g., Wallace*, 2018 U.S. Dist. LEXIS 203441, at *21 (denying motion to dismiss where plaintiff alleged that manufactured widely advertised mesh product as safe, and that "it failed to disclose to physicians that 'its mesh was subject to material changes in polypropylene and/or cause erosion or excessive scar tissue and/or fibrotic formation,' which caused [plaintiff's] injuries.").

"[A]n express warranty must be 'directed at consumers in order to induce purchases of the product.'" *Sowers v. Johnson & Johnson Med.*, 867 F. Supp. 306, 314 (E.D. Pa. 1994) (quoting *Kenepp v. Am. Edwards Lab.*, 859 F. Supp. 809, 817 (E.D. Pa. 1994)). "Absent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised, a claim for breach of express warranty is not sufficiently pled." *Gross*, 858 F. Supp. 2d at 501-02 (citation omitted). Here, as elsewhere, a mere recitation of the elements of a cause of action, without such supporting facts, is insufficient to withstand a motion to dismiss. *Id.* at 502; *see also Simmons v. Stryker Corp.*, 2008 U.S. Dist. LEXIS 93306, at 6-7 (D.N.J. Nov. 17, 2008) (dismissing breach of express warranty claim where plaintiff had done no more than "generally identif[y] the source of the alleged warranty (e.g., publications, package inserts, advertising)," concluding that "this general identification was not sufficient to survive a motion to dismiss.").

b. Prerequisite of notification

In addition, as a prerequisite to bringing a claim of breach of express warranty, a buyer must "within a reasonable time after [s]he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." 13 Pa. Cons. Stat. Ann. § 2607(c)(1); *see Beneficial Commercial Corp. v. Brueck*, 23 Pa. D. & C.3d 34, 39 (Pa. Ct. Com. Pl. 1982) ("[R]easonable notification is a condition precedent to recovery, and, therefore, the claimant has the burden of pleading compliance with Section 2607(c)'s requirements.").

"[T]he purpose of notification under § 2607(c) is to allow the seller an opportunity to resolve the dispute regarding an alleged breach before the buyer initiates a lawsuit." *Kee*, 871 F. Supp. 2d at 410 (quoting *Am. Fed'n of State Cnty. & Mun. Emps. ("AFSCME") v. Ortho-McNeil-Janssen Pharm., Inc.*, 2010 WL 891150, at *6 (E.D. Pa. Mar. 11, 2010)). Additionally, "[s]ection 2607(c)'s requirement that the buyer notify the seller of the breach within a reasonable time after he discovers or should have discovered the breach gives the manufacturer the opportunity to cure the defect, settle the claim through

negotiation, and gather information that may assist in defending the claim." *Beneficial Comm. Corp.*, 23 Pa. D. & C.3d at 37.

A plaintiff bears the burden to prove compliance with § 2607. *Kee*, 871 F. Supp. 2d at 410 (citing *Vanalt Elec. Constr. Inc. v. Selco Mfg. Corp.*, 233 F. App'x 105, 108-10 (3d Cir. 2007)). At the motion to dismiss stage, a plaintiff "must 'plead, at a minimum, . . . that [she] provided reasonable notification . . . to state a viable claim for recovery . . . or be barred from any remedy.'" *Id.* (quoting *AFSCME*, 2010 WL 591150, at *7).

Mills does not maintain that the complaint actually pleads that notice was given. Instead, she argues that defendants had notice in fact—*i.e.*, "actual knowledge of the defects that causes Plaintiff's injuries." (PABr at 18). That argument was raised and rejected by the court in *AFSCME*, 2010 WL 891150 at *6 ("Plaintiffs' argument, however, that notification under § 2607(c) is unnecessary because Defendants had actual or constructive knowledge of the breach, is not supported by the language of the UCC, its statutory purpose, or existing case law interpreting § 2607.").[17]

The plaintiff in *AFSCME* argued that defendants were aware of the defect because "it was Defendants themselves who first gave notice to the purchasers that the [product was] defective through the recall notice." *Id.* at *18. The court rejected plaintiff's argument that defendant's actual notice or knowledge of the breach satisfied § 2607(c)(1). To have "notice" of something, the court stressed, is distinct from the requirement that one be "notified" of it:

> Plaintiffs appear to confuse the term "notice" with "notify"—which the UCC explicitly distinguishes. Under UCC § 1202(a), a person has *notice* of a fact when the person has actual knowledge of it, has received notification of it, or, from all of the facts and circumstances known to that person at the time in question, has reason to know it exists. On the other hand, § 1202(d) defines *notify* to mean "give a notice or notification to another person by taking such steps as may be reasonably required to inform the

---

17 13 Pa. Cons. Stat. Ann. § 2607(c)(1), recall, is equivalent to UCC 2-607(c)(1).

other person in ordinary course, whether or not the other person actually comes to know of it."

Id. at *6.

The requirement of the affirmative act of "notification" has its own specialized purpose:

> The purpose of notification under § 2607(c)(1) is not intended to merely make the seller aware of the breach; rather, the notification must "inform [ ] the seller that the transaction is claimed to involve a breach, and thus opens the way for normal settlement through negotiation." [quoting §2607(c) cmt. 4] Thus, the purpose of notification under § 2607(c) is to allow the seller an opportunity to resolve the dispute regarding an alleged breach before the buyer initiates a lawsuit.

Id.

It was on that basis, then, that *AFSCME* reasoned that even a defendant aware of a defect "may not have been aware of Plaintiffs' intent to file a class action lawsuit, and [was therefore] denied the opportunity to negotiate or settle this claim without judicial involvement." *Id.* The notification requirement under the statute "requires the affirmative act of notification, and Section 2607(c)(1) explicitly requires the buyer to 'notify the seller of breach or be barred from any remedy.'" *Id.* Therefore, the court rejected the plaintiffs' "constructive notice" argument and dismissed the breach of warranty claim.

At the motion to dismiss stage, a plaintiff is not required to "allege in the Complaint that the notification occurred in any substantial form (such as a letter or a formal demand), as the 'reasonableness' of the notice is a factual matter left for the jury to resolve." *Id.* at *7 (citing *Vanalt Electrical Constr., Inc. v. Selco Mfg. Corp.*, 233 Fed. Appx. 105, 111 (3d Cir. 2007)). However, at a minimum, a plaintiff must allege that he or she "notified Defendants in some manner" as a condition precedent to any remedy. *Id.*[18]

---

18 *See generally* Fed. R. Civ. P. 9(c):

> (c) Conditions Precedent. In pleading conditions precedent, it suffices to allege generally that all conditions precedent have occurred or been

Mills does not allege, even generally, that she provided defendants with notification as required by § 2607(c)(1). I agree with the reasoning in *AFSCME* and will dismiss count four, the express warranty claim, without prejudice.

c. Allegation of affirmation of fact or promise

Count four of the complaint also fails to make an adequate allegation of an "affirmation of fact or promise made by" the defendants, required to set forth a claim of express warranty under Pennsylvania law. It will be dismissed for this additional and alternative reason. A plaintiff bringing an express warranty claim is saying that she bought the product based on a statement or promise by the defendant that turned out to be untrue. It is not too much to expect the plaintiff to identify that statement or promise.

The allegations of an affirmative representation in this complaint are as follows. Mills alleges that "Defendants expressly warranted through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their hernia mesh devices were safe" and "expressly warranted that their hernia mesh devices were safe for their intended use and as otherwise described in this complaint." (Compl ¶¶117-18). Mills further claims that "Defendants represented that the products used for hernia repair were safer and more efficacious than other alternative surgical approaches and techniques" and that "Defendants made false material representations and/or material omissions through the course of an aggressive sales and marketing operation that implemented false and misleading statements by sales representatives, Defendant-sponsored literature, and/or Defendant-sponsored promotional functions." (Compl ¶¶120, 124).

These allegations do little more than track the elements of a claim. Such a statement can be identified and described by the plaintiff, *ex hypothesi* the person to whom it was made. The complaint fails to do this.

---

performed. But when denying that a condition precedent has occurred or been performed, a party must do so with particularity.

Other courts have dismissed breach of express warranty claims based on similar boilerplate allegations of affirmative representations or promises. *See McPhee*, 989 F. Supp. 2d at 466 (dismissing express warranty claim where plaintiff alleged that defendants "expressly warranted that the device was safe, effective, durable, free from defects, merchantable, and fit and proper for its intended use" and that these warranties "were made through various sources which Plaintiffs generally and without specificity describe to include Defendant, its authorized agents or sales representatives, publications, package inserts, the internet and other communications intended for physicians, medical patients, and the general public."); *Horsmon*, 2011 U.S. Dist. LEXIS 130415, at *10-11 (dismissing express warranty claim where plaintiff generally alleged that "defendants expressly warranted in its written literature, advertisements and representations of its representatives and agents that its acetabular systems, bone screws, liners and other related components were safe, effective, fit, and proper for the use for which they were intended."); *Kester*, 2010 U.S. Dist. LEXIS 59869, at *31 (dismissing breach of express warranty claim where "Plaintiff neither specifies any particular promise that formed the basis of her bargain with the Defendants, who are generically and collectively named, nor does she demonstrate any promise was directed at her, as a consumer, to induce her into purchasing the product."); *cf. Simmons v. Stryker Corp.*, 2008 U.S. Dist. LEXIS 93306, at *2 (D.N.J. Nov. 17, 2008) (applying New Jersey law and dismissing breach of express warranty claim where plaintiff alleged that defendant warranted that product was "fit, safe, and effective and proper for the purpose for which it was to be used.").

Mills's allegations, as currently pled, do not meet minimal pleading standards for setting forth a claim of breach of an express warranty. On this independent ground, then, count four is dismissed without prejudice to the submission, within 30 days, of a motion to amend.[19]

---

19 Anticipating an affirmative statute of limitations defense, the complaint also alleges that the doctrine of equitable tolling based on fraudulent concealment applies. Defendants contend that Mills has not sufficiently set forth allegations of the "time,

C. Getinge AB's motion

Getinge AB, like AMC and Maquet, would be entitled to dismissal of all counts for the reasons stated in the preceding section. Getinge AB also seeks dismissal of the complaint as to itself on two interrelated grounds: (1) Mills improperly effectuated service by serving its in-state subsidiary and did not translate the complaint into Swedish, as required by the Hague Convention; and (2) Getinge AB is not subject to personal jurisdiction in New Jersey.

To serve Getinge AB, Maquet, and AMC, Mills sent a copy of the complaint and summons by certified mail to "c/o National Registered Agents" at "160 Greentree Dr., STE 101, Dover, DE 19904." (DE 18-20). Mills does not dispute that she attempted to serve Getinge AB by mailing a copy of the summons and complaint to Maquet's registered agent in Delaware. She asserts that this was adequate service. (PGBr at 1).

In the absence of service of process or a waiver of service by the defendant, due process will not permit a court to exercise power over a party named as defendant in the complaint. *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 350 (1999). Once a challenge to the sufficiency of service is lodged, "the party asserting the validity of service bears the burden of proof on that issue." *Grand Entm't Grp., Ltd. v. Star Media Sales, Inc.*, 988 F.2d

---

place, and content" of the alleged false or fraudulent representations" or "affirmative misrepresentations and omissions" regarding the risks associated with the hernia mesh device. (DABr at 19). Because I have dismissed all of Mills's claims, I do not address this issue. However, I note that the Third Circuit typically resolves equitable tolling issues at the summary judgment stage, given the fact-sensitive nature of the inquiry. "[B]ecause the question whether a particular party is eligible for equitable tolling generally requires consideration of evidence beyond the pleadings, such tolling is not generally amenable to resolution on a Rule 12(b)(6) motion." *Drennan v. PNC Bank, N.A.*, 622 F.3d 275, 301-02 (3d Cir. 2010) (citing *Huynh v. Chase Manhattan Bank*, 465 F.3d 992, 1003-04 (9th Cir. 2006) ("Generally, the applicability of equitable tolling depends on matters outside the pleadings, so it is rarely appropriate to grant a Rule 12(b)(6) motion to dismiss (where review is limited to the complaint) if equitable tolling is at issue."); *Reiser v. Residential Funding Corp.*, 380 F.3d 1027, 1030 (7th Cir. 2004) (rejecting argument that plaintiffs' claims were untimely under the applicable limitations periods and noting that "because the period of limitations is an affirmative defense it is rarely a good reason to dismiss under Rule 12(b)(6)")).

476, 488 (3d Cir. 1993). This burden can be met by a preponderance of the evidence using affidavits, depositions, and oral testimony. *State Farm Mut. v. Tz'Doko V'Chesed*, 543 F. Supp. 2d 424, 428 (E.D. Pa. 2008) (citation omitted). "[W]here service of process is found to be ineffective, the court has discretion to either dismiss or quash service which has been made." *Dimensional Commc'ns, Inc. v. OZ Optics Ltd.*, 218 F. Supp. 2d 653, 655 (D.N.J. 2002); *see also Cephalon, Inc. v. Sun Pharm. Indus.*, 2011 U.S. Dist. LEXIS 140580, at *4 (D.N.J. Dec. 7, 2011) ("If service of process was not sufficient, the Court has discretion to dismiss the action, but dismissal is not mandatory.").

Service upon foreign defendants is governed by Federal Rule of Civil Procedure 4(h)(1), which provides two acceptable methods for serving a "domestic or foreign corporation ... in a judicial district of the United States." "Those methods are 'in the manner prescribed by Rule 4(e)(1) for serving an individual' or 'by delivering a copy of the summons and complaint to an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process and—if the agent is one authorized by statute and the statute so requires—by also mailing a copy of each to the defendant.'" *Erie Ins. Exch. v. Gree USA, Inc.*, 2019 U.S. Dist. LEXIS 53133, at *5 (M.D. Pa. Mar. 28, 2019); *see Cephalon*, 2011 U.S. Dist. LEXIS 140580, at *4.

Rule 4(e)(1) provides that service may also be accomplished by "following state law for serving a summons in an action brought in courts of general jurisdiction in the state where the district court is located or where service is made." New Jersey Court Rule 4:4-4(a)(6) provides that personal jurisdiction can be obtained over a foreign corporation by "serving a copy of the summons and Complaint on any officer, director, trustee or managing or general agent, or any person authorized by appointment or by law to receive service of process on behalf of the corporation." N.J. Ct. R. 4:4-4(a)(6); *see Dewey v. Volkswagen AG*, 558 F. Supp. 2d 505, 512 (D.N.J. 2008). "Thus, both Rule 4(h) and New Jersey law permit service of process upon a foreign corporation by serving an

agent of the foreign corporation who is authorized by appointment or by law to receive it." *Dewey*, 558 F. Supp. 2d at 512.

The Federal Rules of Civil Procedure additionally provide for service outside of the judicial district. In that scenario, service may be effectuated "in any manner prescribed by Rule 4(f) ["Serving an Individual in a Foreign Country"] for serving an individual, except personal delivery under (f)(2)(C)(i)." Fed. R. Civ. P. 4(h) (alteration added). Rule 4(f) provides, in turn, for service to be effectuated "by any internationally agreed means of service that is reasonably calculated to give notice, such as those authorized by the [Hague Convention]." *Erie Ins. Exch.*, 2019 U.S. Dist. LEXIS 53133, at *6 (internal quotation and citation omitted).

Getinge AB suggests that service upon a foreign corporation can only be made pursuant to the Hague Convention, which was not complied with here. (DGBr at 4). As explained above, however, the Federal Rules provide alternative means of service on a foreign corporation aside from compliance with the Hague Convention. In *Volkswagenwerk Aktiengesellschaft v. Schlunk*, 486 U.S. 694 (1988), the Supreme Court held that service on a foreign corporation did not have to comport with the Hague Convention "[w]here service on a domestic agent is valid and complete under both state law and the Due Process Clause." *Id.* at 707. The Court explained that "there is no . . . evidence in the negotiating history that the Convention was meant to apply to substituted service on a subsidiary . . . . which clearly does not require service abroad under the forum's internal law." *Id.* at 704. In other words, if service "under state law, [does] not necessarily require transmittal of the relevant documents [abroad], the Hague Service Convention simply [is] not implicated." *Erie Ins. Exch.*, 2019 U.S. Dist. LEXIS 53133, at *8 (alterations in original). Therefore, I turn to whether service on Maquet was sufficient to effectuate service upon Getinge AB under state law.

"Under New Jersey law, service on a wholly owned subsidiary confers jurisdiction over the foreign parent only if the subsidiary is an alter ego or

agent of the parent." *Dewey*, 558 F. Supp. 2d at 513 (citing *Patent Incentives, Inc. v. Seiko Epson,* Corp., 1988 U.S. Dist. LEXIS 9933 (D.N.J. Sept. 6, 1988), *aff'd*, 878 F.2d 1446 (Fed. Cir. 1989)); *see Cephalon, Inc.*, 2011 U.S. Dist. LEXIS 140580, at *8.

In determining whether a subsidiary is acting as an agent of the parent, the court must consider four factors: "(1) whether the subsidiary is doing business in the forum that would otherwise be performed by the parent; . . . (2) whether there is common ownership of the parent and subsidiary; (3) whether there is financial dependency; and (4) whether the parent interferes with the subsidiary's personnel, disregards the corporate formalities, and/or controls the subsidiary's marketing and operational policies." *Dewey*, 558 F. Supp. 2d at 513 (internal citation omitted) (citing *Seltzer v. I.C. Optics, Ltd.*, 339 F. Supp. 2d 601, 609-10 (D.N.J. 2004); *Cintron v. W&D Machinery, Co., Inc.*, 440 A.2d 76, 80 (N.J. Super Ct. Law Div. 1981) (stating that subsidiary that is a "mere instrumentality of the foreign corporation . . . should be held to occupy the status of a managing agent of the foreign corporation within the meaning of statutory provisions authorizing service of process upon a managing agent of a corporation.")).

In determining whether a subsidiary is an alter ego of its parent, the court must consider whether "the parent so dominated the subsidiary that it had no separate existence but was merely a conduit for the parent." *State, Dep't of Envtl. Prot. v. Ventron Corp.*, 468 A.2d 150, 164 (N.J. 1983). "[E]ven the exercise of significant control by the parent over the subsidiary will not suffice to pierce the corporate veil" under New Jersey law. *Craig v. Lake Asbestos of Quebec, Ltd.*, 843 F.2d 145, 150 (3d Cir. 1988). To pierce the corporate veil, New Jersey law generally requires that the parent corporation have "abused the privilege of incorporation by using the subsidiary to perpetuate a fraud or injustice, or otherwise to circumvent the law." *Patent Incentives, Inc.*, 1988 WL 92460, at *6 (citing *Ventron*, 468 A.2d at 164).

In *Dewey*, the district court found that the relationship between Volkswagen of America ("VWOA") and Volkswagen of Germany ("VWAG") was "so close that VWOA operates as an agent of VWAG by law for the purpose of service of process." 558 F. Supp. 2d at 513. In that case, the plaintiff submitted an affidavit that demonstrated the following: (1) "VWAG owns 100% of the outstanding stock of VWOA"; (2) VWOA is the sole authorized U.S. importer and distributor of cars manufactured by VWAG; (3) VWAG has the power to appoint VWOA's President and CEO; and (4) the Importer Agreement governing the relationship between VWAG and VWOA demonstrated that VWAG had substantial control of VWOA's activities, including not only matters related to the "importation of VWAG vehicles," but also the "marketing, distribution and sales of VWAG vehicles," the proliferation of dealerships, "the training of dealership personnel," and terms of payment between individual customers and VWOA. *Id.* at 513-14.

Based on all of these factors, the court held, "it is apparent that VWAG cannot do business in the United States absent its wholly owned subsidiary . . . [and that] the VWOA is an agent of VWAG by law for service of process because 'the subsidiary is doing business in the forum that would otherwise have to be done in the forum by the parent.'" *Id.* at 514; *cf. Cephalon, Inc.*, 2011 U.S. Dist. LEXIS 140580, at *8 (holding that service on New Jersey subsidiary insufficient for service on parent corporation where plaintiff did not provide "affidavit demonstrating that [parent company] has substantial control over [in-state subsidiary's] operations or sales; that [parent] has the power to appoint the president of [subsidiary]; or that [subsidiary] is 'doing business in the forum that would otherwise have to be done in the forum by the parent.'").

Mills's alter ego and agency arguments pale in comparison. The complaint alleges that "Defendant GETINGE AB is a corporation organized and/or existing under the laws of the Federal Republic of Sweden with its principal place of business in Getinge, Sweden," and that Getinge AB owns all of the common stock "and other ownership interests of" Maquet. (Compl ¶¶19, 22). Mills claims "[o]n information and belief, Defendant ATRIUM MEDICAL

CORPORATION, Defendant MAQUET CARDIOVASCULAR, and Defendant GETINGE AB were the agents, representatives, joint ventures, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other." (Compl ¶23). This allegation is barely factual at all; it amounts to no more than a legal conclusion. Aside from these introductory paragraphs, the rest of the complaint simply refers to the defendants collectively. It contains no specific factual allegations related to Getinge AB. Mills does not allege any specific conduct or contacts on the part of Getinge AB within New Jersey.

Mills's opposition brief asserts that "information available in the public domain" suggests that Getinge was properly served as Maquet's alter ego. (PGBr at 1). Getinge AB acquired Maquet in 2011, and Maquet is the "largest subsidiary" of Getinge AB. (PGBr at 2-3). Getinge AB is also the "sole member" of Maquet. (PGBr at 6). Mills further asserts that, in 2017, Getinge AB issued a press release suggesting that it was taking the "next steps" to unify its various brands, including Maquet, under "the Getinge brand."[20] Pursuant to this unification effort, "[a]ll of the group's products will carry the Getinge logo in the future" and some "of the current brands within the Getinge Group, such as Maquet, will become product family names under the Getinge master brand."

With respect to the first agency factor (whether the subsidiary is doing business in the forum that would otherwise be performed by the parent), Mills cites no facts. Mills has not pointed to any evidence to suggest a "financial dependency" between Getinge AB and Maquet (third factor) or that Getinge AB interferes with Maquet's personnel or controls Maquet's "marketing and operational policies" (fourth factor). Mills simply notes Getinge AB is the only member of Maquet LLC. She cites no case in which being a member or sole member of an LLC is sufficient to impute alter ego status. *Cf. Leo v. Kerr—McGee*, 1996 WL 254054, at *6 (D.N.J. May 10, 1996) (noting that even "[a]

---

20 *See* Getinge AB, "Getinge establishes new brand structure and becomes a single brand company (Mar. 20, 2017)," https://www.getinge.com/int/about-us/press/news/press-releases/2017/2498283-Getinge-establishes-new-brand-structure-and-becomes-a/.

significant degree of overlap between directors and officers of a parent and its subsidiary does not establish an alter ego relationship." (citing *Patent Incentives*, 1988 WL 92460, at *7)).

Similarly, the fact that the parent and subsidiary share the same "brand" is insufficient. *See Horowitz v. AT&T Inc.*, 2018 WL 1942525, at *9 (D.N.J. Apr. 25, 2018) ("[a]ccepting Plaintiffs' position would extend the alter ego doctrine, such that entities utilizing the same brand, website, and policies would be imputed as alter egos."); *see also Laverty v. Cox Enters.*, Civ. No. 18-1323 (FLW) (TJB), 2019 U.S. Dist. LEXIS 13588, at *11-12 (D.N.J. Jan. 29, 2019) (holding that subsidiary was not alter ego of subsidiary where plaintiff relied "on general corporate and marketing statements that vaguely touch on the relationship" between parent and subsidiary).

Accordingly, because Mills has not shown that Getinge AB "so dominated [Maquet] that it had no separate existence but was merely a conduit for the parent," her alter ego theory fails. *See Seltzer*, 339 F. Supp. 2d at 610 (citing *Ventron*, 468 A.2d at 164). Therefore, the Court finds that service on Maquet in New Jersey was insufficient to impute service on Getinge AB and dismissal of the complaint as to Getinge AB is warranted on this additional basis.[21] This dismissal is without prejudice.

V. Conclusion

For the reasons provided above, the defendants' motions are granted. (DE 25, 26). The following claims are dismissed with prejudice as to all

---

21 Because Getinge AB has not even been validly served, I do not address its personal jurisdiction arguments. Mills raises similar arguments for imputation or alter ego based on Getinge AB's relationship with Maquet to establish personal jurisdiction over Getinge AB. Mills requests jurisdictional discovery "before the Court resolves any disputes regarding Defendant's actual relationship to the forum defendant." (PGBr at 1). Such jurisdictional discovery is not appropriate where, as here, Mills has not served the named defendant, and has not put forth a minimal showing suggesting entitlement to discovery on the issue of personal jurisdiction. *Hansen v. Neumueller GmbH*, 163 F.R.D. 471, 476 (D. Del. 1995); *cf. Eurofins Pharma US Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 156 (3d Cir. 2010) ("being the foreign parent of a Delaware subsidiary, without more, is insufficient to confer personal jurisdiction over a nonresident defendant under the Delaware long-arm statute.").

defendants: strict liability for defective design (second count); strict liability for failure to warn (third count); breach of the implied warranty of fitness for a particular purpose (fifth count); and breach of the warranty of merchantability (sixth count).

The remaining counts, negligence and breach of an express warranty (first and fourth counts) are dismissed without prejudice.

I also conclude that service on Getinge AB was deficient. Accordingly, dismissal of the complaint at to Getinge AB is warranted for this additional reason. This dismissal is also without prejudice.

An appropriate order follows.

Dated: August 27, 2019

KEVIN MCNULTY
United States District Judge